DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

April 8, 2016

Hospira, Inc
Ms. Yuliya Matlin
Associate Director, Global Regulatory Affairs
275 North Field Drive
Lake Forest, Illinois 60045

Re: K143612
Trade/Device Name: Lifecare PCA™ Infusion System
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: MEA, FPA
Dated: March 4, 2016
Received: March 10, 2016

Dear Ms. Matlin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tina Kiang -S

for Erin I. Keith, M.S.
Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143612

Device Name
LifeCare™ PCA Infusion System

Indications for Use *(Describe)*
The LifeCare PCA™ infusion system is intended for intravenous or epidural administration of analgesic medications that are delivered by a continuous rate of infusion and/or with patient-controlled demand doses.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k)
SUMMARY

A summary of 510(k) information in accordance with the requirements of 21 CFR 807.92 is provided below for K143612.

Submitter Information	
Name	Hospira, Inc.
Address	275 North Field Dr., Lake Forest, IL 60045
Phone number	858-391-1142
Fax number	224-212-5401
Establishment Registration Number	3005579246
Name of contact person	Yuliya Matlin
Date prepared	April 5, 2016
510(k) Number	K143612
Name of device	
Trade or proprietary name	LifeCare PCA™ Infusion System
Common or usual name	Patient Controlled Analgesia (PCA) Infusion Pump and Administration Sets
Classification name	Infusion Pump
Classification panel	General Hospital
Regulation	21 CFR 880.5725 (Infusion Pump)
Product Code(s)	MEA - Patient Controlled Analgesia (PCA) Infusion Pump FPA - Administration Sets
Legally marketed device(s) to which equivalence is claimed	Hospira LifeCare™ PCA3 Infusion System, cleared under K043256 Hospira LifeCare PCA™ Infusion Pump System with Hospira MedNet™ Software cleared under K042800 No Reference Devices were used in this submission

Device description	The Hospira LifeCare PCA™ Infusion System is a microprocessor controlled, pole mounted, electromechanical infusion pump that allows a patient to self-administer analgesic using an attached patient pendant, within physician prescribed, programmed parameters. The Hospira LifeCare PCA™ Infusion System also includes a sterile empty vial that can be pharmacy-filled with appropriate medications, and dedicated administration sets to administer the medication. The infuser is powered from an AC power source and has an internal battery to maintain operation for short periods when an AC power source is not available. A stepper motor exerts pressure on an inserted drug vial to control the infusion of analgesic into a patient. The infuser will accept either a pre-filled drug vial manufactured by Hospira or a sterile empty vial that can be filled by a hospital's pharmacy. Administration Sets compatible for use in the LifeCare PCA™ Infuser are provided sterile (fluid path) and intended for single-use application. The infuser is equipped with wireless (802.11 a/b/g) and wired interfaces to Hospira MedNet™ Software. Drug Libraries and Auto-Programs are transferred using these interfaces. The subject device bi-directionally communicates to the hospital information system through the Hospira MedNet™ Server, which is optional software, and the device can also be programmed and used without the Hospira MedNet™ software.
Indications for Use	The LifeCare PCA™ infusion system is intended for intravenous or epidural administration of analgesic medications that are delivered by a continuous rate of infusion and/or with patient-controlled demand doses.
Summary of Intended Use Compared to Predicate Device	The indication for use is nearly identical to the predicate. The difference in the intended use statements of the predicate and subject device clarifies that the subject device may deliver continuous or patient controlled administration of analgesic medications via intravenous or epidural routes of administration. This change in wording does not alter the function of the device in comparison to the predicate and is intended to provide clarity to the device's functionality.
Summary of Technological Characteristics Compared to Predicate Device	The LifeCare PCA™ Infusion System with Hospira MedNet™ employs the same fundamental scientific technology, and principles of operation and intended/indications for use as are used by the predicate device(s). In addition, the LifeCare PCA™ Infusion System has the following technological characteristics comparable to predicate device(s) which previously received 510(k) clearance: • Utilize the same pumping technology; deliver fluids over the same flow rates with same accuracy. • Have similar drug library features and wired and wireless communication options using a facility's network infrastructure. • Incorporates the same basic Infusion System design with the exception of the design updates described in this 510(k). • Incorporate the same basic software driven electronic control system • Use comparable dedicated administration sets.

Summary of Technological Characteristics Compared to Predicate Device (Continued)	Modifications to the software, hardware, labeling, and PCA consumables as compared to the predicate device include: Software: Changes to the user interface to enhance auto-programming workflow. Alarm risk prioritization (low, medium, high) and alarm visual indicator updates to comply with IEC 60601-1 Edition 3. Addition of wireless strength and battery capacity indicators. Updates to the Biomed capabilities to include more diagnostic information and usage counters. Improvements to the wireless connectivity to include global region support, enhanced roaming, and to update wireless system components. Implement cybersecurity enhancements. Hardware: Miscellaneous changes to hardware to comply with IEC60601-1 Edition 3. Strengthened door and latch design. Material change to half nut/lead screw. Added seal around barcode reader window to prevent fluid ingress. Labeling: Updates to the System Operating Manual, Technical Service Manual and on pump label to align with IEC 60601-1 Edition 3 and to incorporate updated workflow for auto-programming. Updates to Sterile Empty vial providing guidelines for barcode label placement after filling with medication. PCA Consumables: modified distal male luer adaptor design on all administration sets. Increased activation pressure for the Pressure Activated Valve (PAV). Changed slide clamp color to orange.
Performance Data – Non Clinical Testing	An assurance case was provided for the LifeCare PCA™ Infusion System as recommended in the FDA guidance document, Infusion Pumps Total Product Life Cycle. The stated goal of the assurance case is: • The LifeCare PCA™ infusion system design is adequately safe for its intended use. The assurance case defined the device system, including the indications for use, system definition, operational description, patient populations, and use environments. The supporting assurance arguments covered the following attributes: • Residual risks are analyzed and determined to be acceptably low • Design is verified and valid for its indications for use as it relates to safety • Device design is reliable

<table>
<tr><td>Performance Data – Non Clinical Testing (Continued)</td><td>The following evidence was included in the assurance case:

Performance Test Summary
System verification and validation activities for LifeCare PCA™ Infusion System confirmed that the system meets user needs and design inputs. All the testing met the acceptance criteria.

Human factors evaluations have been conducted to validate the effectiveness of use error related mitigations

Software documentation as recommended in the following FDA guidance documents:
• Infusion Pumps Total Product Life Cycle
• Content of Premarket Submissions for Software Contained in Medical Devices
• Content of Premarket Submissions for Management of Cybersecurity in Medical Devices

Biocompatibility evaluations of consumable products were conducted in accordance with
• ISO 10993-1:2009 (Corrigendum 2010)
• FDA Draft Guidance for Industry and Food and Drug Administration Staff Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing" issued April 2013

Electrical and Electromagnetic Compatibility testing were conducted. The Infusion System complies with following standards:

<table>
<tr><td>Basic Safety and Essential Performance</td><td>ANSI/AAMI ES60601-1:2005/(R) 2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012,</td></tr>
<tr><td>Electromagnetic Compatibility</td><td>IEC Standard 60601-1-2:2007 3rd Ed.</td></tr>
<tr><td>Alarm Systems</td><td>IEC 60601-1-8, Edition 2.1 2012-11</td></tr>
<tr><td>Infusion Pump Basic Safety and Essential Performance</td><td>IEC 60601-2-24 Medical Electrical Equipment – Part Edition 2.0 2012-10</td></tr>
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<tr><td>Performance Data – Clinical Testing</td><td>Clinical evaluation is not required for this submission to support substantial equivalence. Human Factors studies have been conducted on subject devices, demonstrating passing results.</td></tr>
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CONCLUSIONS DRAWN FROM CLINICAL AND NON-CLINICAL DATA

The conclusions drawn from the nonclinical and clinical tests demonstrate that the device is substantially equivalent to the predicate devices.